



1FW

Docket No.: 1289-002 US.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
PATENT OPERATIONS

In re Application of: )  
 )  
 **Orapin P. Rubino, et al.** ) Group Art Unit: 1615  
 )  
 Serial No.: 10/728,196 ) Examiner: --  
 )  
 Filed: December 4, 2003 )

For: **METHOD OF PREPARING BIOLOGICALLY ACTIVE  
FORMULATIONS**

New York, NY 10036  
October 7, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

This Information Disclosure Statement is being filed under the provisions  
of 37 CFR§1.97.

US 6,558,704	Discloses process for preparing pellets containing up to 90 WT.% of a pharmaceutical active ingredient.
US 6,224,909	Discloses fast decomposing pellets.
US 6,197,347	Discloses oral dosage for the controlled release of analgesic.
US 6,238,703	Discloses controlled release oral dosage form of ketoprofen.
US 5,084,287	Discloses pharmaceutically useful micropellets with a drug-coated core and controlled release polymeric coat.
US 5,709,885	Discloses process for the preparation of drug pellets.
US 5,503,845	Discloses tablets, granulates and pellets with a high active substance content for highly concentrated, solid dosage forms.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.H./

US 6,132,769	Discloses pharmaceutical matrix pellets, tablets and composition for the preparation thereof.
US 5,807,583	Discloses process for the preparation of sustained release pellets.
US 5,807,579	Discloses pseudoephedrine combination pharmaceutical compositions.
WO 91/18590	Discloses process for the manufacture of porous cellulose matrices.
WO 93/07859	Discloses novel pharmaceutical pellets and process for their production.
EP 0 701 815	Discloses process for producing powders, granulates or pellets containing active substances and a structure consisting of hydrophilic macromolecules, and use thereof.
WO 94/28882	Discloses multiparticulate pulsatile drug delivery system.
WO 95/34291	Discloses pellets.
WO 00/33819	Discloses method for producing agglomerates comprising a core-shell structure.
US 5,292,461	Discloses process for the production of pellets.
US 5,011,640	Discloses process for spheronization and device for implementing said process.
US 6,449,689	Discloses system and method for efficiently storing compressed data on a hard disk drive.
US 4,895,733	Discloses method and system for agglomerating particles and/or for coating particles.
US 5,132,142	Discloses apparatus and method for producing pellets by layering power onto particles.

US 6,354,728

Discloses device for producing a pourable product with a guide vane therein.

Respectfully submitted,



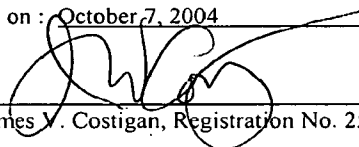
James V. Costigan  
Registration No. 25,669

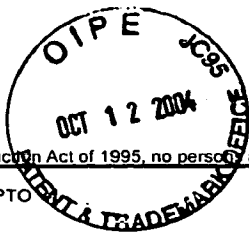
MAILING ADDRESS  
HEDMAN & COSTIGAN, P.C.  
1185 Avenue of the Americas  
New York, NY 10036-2646  
(212) 302-8989

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

on : October 7, 2004

  
James V. Costigan, Registration No. 25,669



PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1

of

1

**Complete if Known**

Application Number	10/728,196
Filing Date	December 4, 2003
First Named Inventor	Orapin P. Rubino, et al
Art Unit	1615
Examiner Name	--
Attorney Docket Number	1289-002 US.1

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA	US- 6,558,704	5/6/2003	Bartholomaeus, et al	
	AB	US- 6,224,909	5/1/2001	Opitz, et al	
	AC	US- 6,197,347	3/6/2001	Jan, et al	
	AD	US- 6,238,703	5/29/2001	Jan, et al	
	AE	US- 5,084,287	1/28/1992	Ghebre-Sellassie, et al	
	AF	US- 5,709,885	1/20/1998	Hellen, et al	
	AG	US- 5,503,845	4/2/1996	Goede, et al	
	AH	US- 6,132,769	10/17/2000	Remon, et al	
	AI	US- 5,807,583	9/15/1998	Kristensen, et al	
	AJ	US- 5,807,579	9/15/1998	Vilkov, et al	
	AK	US- 5,292,461	3/8/1994	Juch, et al	
	AL	US- 5,001,640	4/30/1991	Zanchetta	
	AM	US- 6,449,689	9/10/2002	Corcoran, et al	
	AN	US- 4,895,733	1/23/1990	Imanidis, et al	
	AO	US- 5,132,142	7/21/1992	Jones, et al	
	AP	US- 6,354,728	3/12/2002	Bretschneider, et al	
	AQ	US-			
	AR	US-			
	AS	US-			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	AT	WO 91/18590	12/12/1991	Kabi Pharmacia AB		
	AU	WO 93/07859	4/29/1993	Warner Lambert Co.		
	AV	EP 0 701 815	3/20/1996	Alfatec Pharma GmbH	Abstract only	
	AW	WO 94/28882	12/22/1994	Chen Chih Ming		
	AX	WO 95/34291	12/21/1995	Dumex Ltd As		
	AY	WO 00/33819	6/15/2000	Basf Aktiengesellschaft		

Examiner Signature	/Gigi Huang/	Date Considered	12/17/2009
--------------------	--------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.H./